

EPA Reg. No. 42750-86
Vol. 1

FEE

18 May 2005

SUBJECT: Product Chemistry Review of Clopyralid Technical

FROM: Bruce F. Kitchens, Chemist
Product Chemistry Team
Technical Review Branch/RD (7505C)

Bruce F. Kitchens 18 May 2005
SLM 5719103

TO: RM #23, Joanne Miller/James Stone
Herbicide Branch/ RD (7505C)

DP BARCODE: D306089
EPA REG. NO.: 42750-IA
PC CODE: 117403
REGISTRANT: Albaugh Incorporated
USE: Herbicide Manufacturing Use Product

INTRODUCTION:

The registrant, Albaugh Incorporated, is submitting an application for the registration of the new manufacturing use product, Clopyralid Technical. The active ingredient in this product is Clopyralid at a label nominal concentration of 98.0% a.i. This product is intended for use as in the manufacture of herbicide end-use products. In addition, the registrant states that this product is substantially similar to EPA Reg. No. 62719-80, Lontrel T Technical. In support of this request, the registrant has submitted a basic Confidential Statement of Formula (CSF) dated 29 June 2004, a draft label, and product chemistry data contained in MRID#s 463062-02, -03, -04, and 463109-01. The Technical Review Branch (TRB) has been asked to review this submission.

SUMMARY OF FINDINGS:

TRB has reviewed this submission and reports the following findings:

1. This product is produced from an integrated formulation process. This means that the active ingredient is the result of intended chemical reactions.
2. The impurity profile of the proposed product has been determined and detailed in this report. An impurity of toxicological concern has been identified by the registrant. See confidential appendix.

3. The nominal concentration of the active ingredient listed on the proposed basic CSF and the draft label are the same.
4. The draft label contains the appropriate storage and disposal statements.
5. The active ingredients certified limits as proposed on the basic CSF are acceptable.
6. Comparison of both products reveals that both have the same active ingredient, similar active ingredient nominal concentrations (98% proposed vs 95% cited), and five identical impurities. Both products have the same impurity of toxicological concern. See confidential appendix for details.

CONCLUSIONS:

TRB has reviewed this submission and concludes the following:

1. The basic formula CSF for the proposed manufacturing use product, Clorpyralid Technical dated 29 June 2004 is acceptable.
2. This submission satisfies the data requirements as specified in 40 CFR 158.155, 158.160, 158.162, 158.167, 158.175, and 158.180 with respect to product identity and composition, description of materials used to produce the product, description of production process, discussion of formation of impurities, certified limits, and enforcement analytical method.
3. This submission satisfies the data requirements as specified in 40 CFR 158.190 with respect to physical and chemical properties. The data requirements for storage stability and corrosion characteristics are not satisfied. Inform the registrant that a one-year study is required to satisfy these data requirements. These studies can be conducted concurrently.
4. This product has been determined to be substantially similar to EPA Reg. No. 62719-80, Lontrel T Technical from a product chemistry standpoint only.

REVIEW OF PRODUCT CHEMISTRY, OPPTS 830 SERIES

Chemical Name (IUPAC, ANSI, etc.)	3,6-Dichloro-2-pyridinecarboxylic acid (CAS) 3,6-Dichloropyridine-2-carboxylic acid (IUPAC)
Chemical Numbers (CAS; PC Code)	CAS No. 1702-17-6 PC Code 117403
Registration/Symbol No.	42750-IA
Type of Product (T, FI, MP, EP)	98% MP
DP Barcode	D306089
Reviewer	BKitchens

Albaugh Inc. has submitted (2004; MRID#s 463062-02, -03, -04, and 463109-01) product chemistry data to support a manufacturing use product registration.

Table 1: Manufacturing and Impurity Data for the 98% TGAI				
GLN	Requirement	MRID	Status ¹	Details and/or Deficiency ²
830.1550	Product Identity & Disclosure of Ingredients	463109-01 463062-02	A	This report completely describes the product's identity and composition.
830.1600 830.1620	Starting Materials & Manufacturing Process	463109-01 463062-02	A	Provides a complete description of the product's starting materials and the product's chemical synthesis.
830.1670	Discussion of Impurities	463109-01 463062-02	A	Details the formation of known impurities and provides a discussion of the formation of possible impurities. A discussion of possible penta- and hexachlorobenzenes is also presented.
830.1700	Preliminary Analysis	463109-01 463062-03	A	Provides details of the 5-batch analysis for the active ingredient and its impurities.
830.1750	Certification of Limits	463109-01 463062-02	A	Certification of the identity and composition of the proposed product. Also, see the CSF 6/29/04
830.1800	Analytical Methods	463109-01 463062-03	A	Details the analytical method for the active ingredient and its impurities.
¹ A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable. ² Refer to CBI Appendix A for details.				

Table 2: Physical and Chemical Properties for the 98% TGAI				
GLN	Requirement	MRID	Status ¹	Result ² or Deficiency
830.6302	Color	463109-01 463062-04	A	Cream, Off White
830.6303	Physical State	463109-01 463062-04	A	Solid
830.6304	Odor	463109-01 463062-04	A	None
830.6313	Stability	463109-01 463062-04	A	Product is stable at normal and elevated temperatures when exposed to Al, Cu, Fe, and the acetate salts of aluminum, copper, and iron.

Table 2: Physical and Chemical Properties for the 98% TGAI				
GLN	Requirement	MRID	Status ¹	Result ² or Deficiency
830.6314	Oxidation/Reduction		N/A	Product does not contain oxidizing or reducing agents.
830.6315	Flammability		N/A	Product does not contain flammable components.
830.6316	Explodability		N/A	Product is not potentially explosive.
830.6317	Storage Stability		N	
830.6319	Miscibility		N/A	The product is a solid at room temperature.
830.6320	Corrosion Characteristics		N	
830.7000	pH	463109-01 463062-04	A	1.74 at 25 C
830.7050	UV/Visible Absorption	463109-01 463062-04	A	Molar absorption coefficients of PAI (95%) at 3 maximum absorbances: 9730 L/mol • cm at 221 nm (neutral) 9517 L/mol • cm at 221 nm (acidic) 9882 L/mol • cm at 221 nm (basic)
830.7100	Viscosity		N/A	The product is a solid at room temperature.
830.7200	Melting Point/ Melting Range	463109-01 463062-04	A	150° C
830.7220	Boiling Point/ Boiling Range		N/A	TGAI is a solid at room temperature.
830.7300	Density/ Relative Density/ Bulk Density	463109-01 463062-04	A	0.439 g/cm ³ at 23° C (OECD Method No. 109)
830.7370	Dissociation Constant in Water	463109-01 463062-04	A	pKa = 1.72
830.7570	Partition Coefficient (Octanol/Water)	463109-01 463062-04	A	log P _{ow} = 1.3 at 25 C (99.2% PAI by LC)
830.7840	Solubility	463109-01 463062-04	A	<u>Solubility at 25 C:</u> 9.81 mg/ml in water 455 m g/ml in methanol 107 m g/ml in n-octanol 0.0056 m g/ml in n-hexane (99.2% PAI shake-flask)
830.7950	Vapor Pressure	463109-01 463062-04	A	2.5?? x 10 ⁻⁴ Pa at 32.9° C (99.2% PAI)
¹ A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not applicable. ² For example, "brown" for 830.6302; "155° C" for 830.7200.				

ATTACHMENT: CONFIDENTIAL APPENDIX

DATA PACKAGE BEAN SHEET

Date: 30-Jul-2004

Page 1 of 1

FEE

*** Registration Information ***

Registration: 42750-IA - CLOPYRALID TECHNICAL

Company: 42750 - ALBAUGH INC

Risk Manager: RM 23 - Joanne Miller - (703) 305-6224 Room# CM-2 241

Risk Manager Reviewer: James Stone JSTONE

Sent Date: 12-Jul-2004

Calculated Due Date: 29-May-2005

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R31) NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT CHEMIST)

Ingredients: 117403, Clopyralid(98%)

R31
#16924

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 30-Jul-2004

Due Back: _____

DP Ingredient: 117403, Clopyralid

DP Title: _____

CSF Included: ☒ Yes ☐ NoLabel Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned ToDate InDate Out

Organization: RD / TRB

Administrative Due Date: 26-May-2005

Team Name: ChemNegotiated Due Date: 1-28-05

Reviewer Name: _____

Projected Completion Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

No Studies

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Review application for registration and product chemistry data for new source of technical clopyralid. Is this unregistered source of technical chemically substantially similar to currently registered technical, EPA Reg No 62719-80. Fee for Service



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg.
Number:

42750-86

Date of Issuance:

MAY 17 2005

Term of Issuance:

Conditional

Name of Pesticide Product:

Clopyralid Technical

NOTICE OF PESTICIDE:

 x Registration
 Reregistration
(under FIFRA, as amended)

Name and Address of Registrant (include ZIP Code):

Albaugh, Inc.
1910 Exeter Road, Suite 1
Germantown, TN 38138

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product when the Agency requires all registrants of similar products to submit data.

2. Make the following label changes listed below before you release the product for shipment:

a. Add the phrase, "EPA Reg. No. 42750-86".

b. In the Hazards to Humans section add the following statements:

May be fatal if inhaled. Harmful if absorbed through skin. Avoid contact with skin.

Signature of Approving Official:

Joanne S. Miller

Date:

MAY 17 2005

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EPA Reg. No. 42750-86

d. IF all the Precautionary Statements cannot appear on the front panel add a referral statement similar to the following:

See back panel for additional precautionary statments.

3. Submit one (1) copy of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

4. Submit the results of storage stability (GRN 830.6317) and corrosion characteristics (GRN 830.6320) studies to EPA upon completion.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records. For your assistance enclosed are copies of the scientific reviews.

Joanne I. Miller
Product Manager (23)
Herbicide Branch
Registration Division (7505C)

Enclosure

CLOPYRALID TECHNICAL

For Manufacturing Use Only

ACTIVE INGREDIENT:

clopyralid: 3,6-dichloro-2-pyridinecarboxylic acid 98.0%

INERT INGREDIENTS: 2.0%

TOTAL: 100.0%

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

EPA Reg. No. 42750-appl

EPA Est. xxxxxx-xxx-xxx

Manufactured For:
ALBAUGH, INC.
ANKENY, IA 50021

ACCEPTED
with COMMENTS
In EPA Letter Dated:

MAY 17 2005

Under the Federal Insecticide,
Fungicide, and Rodenticide Act,
as amended, for the pesticide
registered under EPA Reg. No.

~~42750-86~~



PRECAUTIONARY STATEMENTS

HAZARD TO HUMANS AND DOMESTIC ANIMALS

DANGER

Corrosive • Causes Irreversible Eye Damage • Harmful If Absorbed Through Skin Or Inhaled

Avoid contact with skin, eyes or clothing. Do not get in eyes or on clothing. Wear goggles or face shield when handling. Avoid breathing dust. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash clothing before reuse.

Manufacturing Chemical: Do not ship or store with food, feeds, drugs or clothing.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product may only be formulated into manufacturing-use herbicide products or end-use herbicide products for the following uses:

AGRICULTURAL USES

Asparagus, barley, corn, fallow land, grasses, mint, oats, pasture, rangeland, sugar beets, tree plantations, and wheat. This product may be used to formulate products for specific use(s) not listed on this label, except residential turf, if the formulator, user group or grower has complied with U.S. EPA submission requirements regarding the support of such use(s). Consult Albaugh for instructions for formulation and other information.

NON-AGRICULTURAL USES

For use only on non-residential turf such as athletic and recreational sports fields, cemeteries, golf courses, industrial sites, non-cropland, parks, rights-of-way, and roadsides. This product may be used to formulate products for specific use(s) not listed on this label, except residential turf, if the formulator, user group or grower has complied with U.S. EPA submission requirements regarding the support of such use(s). Consult Albaugh for instructions for formulation and other information.

This product **must not** be formulated into manufacturing-use herbicide products or end-use herbicide products for use on residential turf.

If the product is labeled for reformulation into products bearing labeling for turf applications other than residential turf, the label must contain the following statements:

GENERAL USE PRECAUTIONS

- DO NOT use on residential turf.
- DO NOT send clippings to a compost facility.
- DO NOT collect grass clippings for mulch or compost.
- Applicator must give notice to landowners/property managers to not use grass clippings for composting.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage and disposal.

PESTICIDE STORAGE: Store in a cool, dry, well-ventilated area.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or environmental control agency, or the hazardous waste representative at the nearest EPA regional office for guidance.

CONTAINER DISPOSAL: Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

WARRANTY LIMITATIONS AND DISCLAIMER

Albaugh, Inc. warrants that at the time of delivery, the product will conform to its chemical description on the label, that it will pass without objection in the trade under the contract description, that seller will convey good title thereto, and that such product will be delivered free from any lawful security interest, lien or encumbrance.

This is the only warranty made on this product. Albaugh, Inc. EXPRESSLY DISCLAIMS ANY IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND, EXCEPT AS SET FORTH IN THE ABOVE PARAGRAPH, ANY OTHER EXPRESS OR IMPLIED WARRANTIES. Buyer acknowledges the use of its own independent skill and expertise in the selection and use of the product and does not rely on any oral or written statements or representations.

MAY 17 2005

Note to the File on EPA Reg. No. 42750-86:

Although HB has not received TRB's product chemistry review, I checked with Debbie McCall on the status of it. The review is completed but not signed yet. The CSF and product chemistry data are acceptable except for data gaps with storage stability and corrosion characteristics. These two data requirements will be made a condition of the registration.

Joanne I. Miller
Product Manager 23

J. I. M.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

TECHNICAL REVIEW BRANCH
SIMILARITY CLINIC DETERMINATION

August 23, 2004

MEMORANDUM

Subject: Name of Pesticide Product: Clopyralid Technical
 EPA File Symbol: 42750-IA
 DP Barcode: D306091
 Decision No: 345773
 PC Code: 117403 Clopyralid

From: Breann Hanson, Toxicologist *BA*
 Technical Review Branch
 Registration Division (7505C) *SCN*

To: James Stone, RM Team 23
 Herbicide Branch
 Registration Division (7505C)

Applicant: Albaugh, Inc.
 121 NE 18th Street
 Ankeny, IA 50021

FORMULATION FROM LABEL:

<u>Active Ingredient:</u>			<u>% by wt.</u>
117403	clopyralid	CAS No. 1702-17-6	98.0%
<u>Inert Ingredients:</u>			<u>2.0%</u>
Total:			100.00%

ACTION REQUESTED: The Risk Manager requests :

“Cite all for Acutes for Unregistered source of technical clopyralid. For acute tox is this formulation substantially similar to the currently registered technical, EPA Reg No 62719-80?”

BACKGROUND: Albaugh, Inc. has applied for registration of Clopyralid Technical, EPA File Symbol 42750-IA, claiming similarity to Lontrel T Technical, EPA Reg. No. 62719-80. The submission includes a label and CSF for the cited product, 62719-80, and the proposed product, 42750-IA and letter/data matrix from the registrant stating “cite all” for acute toxicity studies. The acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, primary skin irritation, primary eye irritation and dermal sensitization studies (MRIDs 416413-01 through -06) are cited from the review on Lontrel T Technical, EPA File Symbol 62719-80. The toxicity data was reviewed in a previous HED memo (McMahon, HED Project No. 0-1915, 11/14/90). Additional acute toxicity studies were submitted later due to a change in the manufacturing process, but PRS did not review the data because there were no additional impurities of known acute toxicity (Levine, D230210, EPA Reg. No. 62719-80, 10/01/96).

RECOMMENDATIONS: We have evaluated the formulations of the proposed product, 42750-IA, and the cited product, 62719-80, and have found them to be substantially similar. Although the proposed product contains a higher concentration of A.I. (4.0% more) the signal word remains DANGER, regardless. In addition, the proposed uses of 42750-IA are substantially similar to those of 62719-80. The acute toxicity data referenced above may be used to support registration of the new product.

The acute toxicity profile of the product, Clopyralid Technical, EPA File Symbol: 42750-IA, is as follows:

Acute Oral LD50	IV	cited	MRID 41641301
Acute Dermal LD50	III	cited	MRID 41641302
Acute Inhalation Toxicity	II	supplementary*	MRID 41641303
Primary Eye Irritation	I	cited	MRID 41641304
Primary Dermal Irritation	IV	cited	MRID 41641305
Dermal Sensitization	Negative	cited	MRID 41641306

* The study was graded as supplementary due to the particle size of the test material being too large to be adequately respirable according to OECD guidelines. The product, 62719-80, was registered with an acute inhalation toxicity grade of II, and so the proposed product, 42750-IA, must also bear this toxicity grade. No additional acute inhalation toxicity test is required for registration.

NOTE TO RM: The label must have the appropriate “Note to Physician” due to the category I for Eye Irritation.

LABELING: Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System.

PRODUCT ID #: 042750-00086

PRODUCT NAME: Clopyralid Technical

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals:

SIGNAL WORD: DANGER

Restricted Use Pesticide due to toxicity categories. For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification.

Corrosive. Causes irreversible eye damage. Do not get in eyes or on clothing. May be fatal if inhaled. Do not breathe dust. Harmful if absorbed through skin. Avoid contact with skin. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Remove and wash contaminated clothing before reuse.

First Aid:

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

If inhaled:

- Move the person to fresh air.
- If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.
- Call a poison control center or doctor for further treatment advice.

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 2, 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT

OPP Decision Number: D-345773
EPA File Symbol or Registration Number: 42750-IA
Product Name: CLOPYRALID TECHNICAL
EPA Receipt Date: 30-Jun-2004
EPA Company Number: 42750
Company Name: ALBAUGH INC

MORRIS GASKINS
ALBAUGH, INC
ALBAUGH INC
1910 EXETER, SUITE 1
GERMANTOWN, TN 38138-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R31

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

Please remit payment in the amount of: \$ 4,000 to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 360277
Pittsburgh, PA 15251

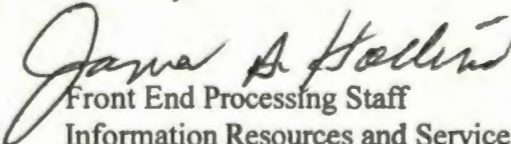
By Courier:
U.S. EPA Washington Finance Center
Pesticide Registration Service Fee
C/O Mellon Client Service Center
500 Ross Street, Room 670
Box 360277
Pittsburgh, PA 15251-6277
Attn: EPA Module Supervisor
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how to request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 305-6249.

Sincerely,


Front End Processing Staff
Information Resources and Services Division

Fee for Service

This package includes the following

for Division

☒ New FFS Action

☒ RD

☐ Amendment

☐ AD

☐ Waiver Request

☐ BPPD

☐ Voluntary Payment Request

Receipt Nos. S- 763004

Product/Risk Manager: 23

EPA File Symbol/Reg. No. 42750-IA

Pin-Punch Date: 6/30/04

☐ This item is NOT subject to FFS action.

Action Code: R-31

Amount Due: \$ 4,000⁰⁰

Voluntary Payment Reduction Amount:

☐ 0%

☐ 40%

☐ 80%

Original Decision #:

☐ 10%

☐ 50%

☐ 90%

☐ 20%

☐ 60%

☐ 100%

☐ 25%

☐ 70%

☐ Other

D- _____

☐ 30%

☐ 75%

_____%

Reviewer: J. Miller

Date: 7/2/04

Remarks:

Data certification form indicates
Cite-All, but they are really going
Selective with "cite-all" option.

FFS cover sheet revision 3



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 42750-xx <u>IA</u>	2. EPA Product Manager J. Miller	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Clopyralid Technical	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) Albaugh, Inc. 1910 Exeter Road Suite 1 Germantown, TN 38138 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>62719-80</u> Product Name <u>Lontrel T Technical</u>	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input checked="" type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

This application is being submitted under the PRIA Fee for Service program as a Class R31 New Product - Me-Too, Non-Fast Track application. Registrant believes this classification is appropriate since it is substantially similar in composition and labeling to an existing registration (noted in Box 6) and is using the Cite-All option for data support. Accordingly, registrant believes the appropriate fee for this application is \$4,000 with 10 month decision timeline.

Please forward invoice to 1-901-309-8532 (fax) and/or e-mail to morrisg@albaughinc.com

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	<input type="checkbox"/> Plastic
				<input type="checkbox"/> Glass	<input type="checkbox"/> Paper
* Certification must be submitted				<input checked="" type="checkbox"/> Other (Specify) <u>plastic lined fiber</u>	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 25 Kg		5. Location of Label Directions <input checked="" type="checkbox"/> On label attached to container	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Morris Gaskins	Title Registrations Manager	Telephone No. (Include Area Code) 901-309-8122	
2. Signature 		3. Title Registrations Manager	
4. Typed Name Morris Gaskins		5. Date 6/29/04	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)	



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number Albaugh, Inc. 121 NE 18th St. Ankeny, IA 50021 800-247-8013	EPA Registration Number/File Symbol 42750-xx 86
Active Ingredient(s) and/or representative test compound(s) clpyralid	Date 6/29/04
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food Use, non-crop	Product Name Clpyralid Technical

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☒ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☐ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 6/29/04	Typed or Printed Name and Title Morris Gaskins Registrations Manager
---------------	------------------------	---

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DATA MATRIX

Date:	EPA Reg. No./File Symbol 42750-appl	Page 1 of 4
Applicant's/Registrant's Name & Address: Albaugh Inc. 121 NE 18 th St. Ankeny, IA 50021	Product: Clopyralid Technical	

Ingredient: Clopyralid acid CAS # 1702-17-6

Guideline Reference	Guideline Study Name	MRID Number	Submitter	Status	Note
830.1550	Product Identity and Composition	With application	Albaugh	OWN	
830.1600	Description of Materials Used to Produce the	With application	Albaugh	OWN	
830.1620	Description of Product Process	With application	Albaugh	OWN	
830.1650	Description of Formulation Process				Waiver ²
830.1670	Description of Formation of Impurities	With application	Albaugh	OWN	
830.1700	Preliminary Analysis	With application	Albaugh	OWN	
830.1750	Certified Limits	With application	Albaugh	OWN	
830.1800	Enforcement Analytical Method	With application	Albaugh	OWN	
830.6302	Color	With application	Albaugh	OWN	
830.6303	Physical State	With application	Albaugh	OWN	
830.6304	Odor	With application	Albaugh	OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	With application	Albaugh	OWN	
830.6314	Oxidation/Reduction: Chemical Incompatibility				Not req'd ¹
830.6315	Flammability				Not req'd ¹
830.6316	Explosibility				Not req'd ¹
830.6317	Storage Stability				Not req'd ¹

Signature 	Name and Title: Morris Gaskins Registrations Manager	Date 6/29/04
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WASHINGTON, DC 20460


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DATA MATRIX

Date: 6/29/04	EPA Reg. No./File Symbol 42750-appl	Page 2 of 4
Applicant's/Registrant's Name & Address: Albaugh Inc. 121 NE 18 th St. Ankeny, IA 50021	Product: Clopyralid Technical	

Ingredient: Clopyralid acid CAS # 1702-17-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6319	Miscibility				Not req'd ¹
830.6320	Corrosion Characteristics				Not req'd ¹
830.6321	Dielectric Breakdown Voltage				Not req'd ¹
830.7000	pH	With application	Albaugh	OWN	
830.7050	UV/Visible Absorption	With application	Albaugh	OWN	
830.7100	Viscosity				Not req'd ¹
830.7200	Melting Point/Melting Range	With application	Albaugh	OWN	
830.7220	Boiling Point/Boiling Range				Waiver ³
830.7300	Density/Relative Density/Bulk Density	With application	Albaugh	OWN	
830.7370	Dissociation Constants in Water	With application	Albaugh	OWN	
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method				Waiver ⁴
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				Waiver ⁴
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography	With application	Albaugh	OWN	

Signature 	Name and Title: Morris Gaskins Registrations Manager	Date 6/29/04
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EPA Form 8570-35 (9-97) Electronic and Paper versions available. Submit only paper version.

Agency Internal Use Copy

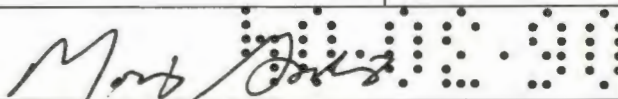
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DATA MATRIX

Date: 6/29/04	EPA Reg. No./File Symbol 42750-appl	Page 3 of 4
Applicant's/Registrant's Name & Address: Albaugh Inc. 121 NE 18 th St. Ankeny, IA 50021	Product: Clopyralid Technical	

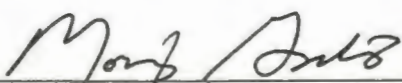

Ingredient: Clopyralid acid CAS # 1702-17-6

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	With application	Albaugh	OWN	
830.7860	Water Solubility, Generator Column Method				Waiver ⁵
830.7950	Vapor Pressure	With application	Albaugh	OWN	
870.1100	Acute Oral Toxicity - Rat	CITE ALL		PAY	
870.1200	Acute Dermal Toxicity - Rat	CITE ALL		PAY	
870.1300	Acute Inhalation Toxicity - Rat	CITE ALL		PAY	
870.2400	Primary Eye Irritation - Rabbit	CITE ALL		PAY	
870.2500	Primary Dermal Irritation	CITE ALL		PAY	
870.2600	Dermal Sensitization	CITE ALL		PAY	
Signature				Name and Title: Morris Gaskins Registrations Manager	Date: 6/29/04

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, DC 20460

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DATA MATRIX

Date: 6/29/04		EPA Reg. No./File Symbol 42750-appl		Page 4 of 4	
Applicant's/Registrant's Name & Address: Albaugh Inc. 121 NE 18 th St. Ankeny, IA 50021		Product: Clopyralid Technical			
Ingredient: Clopyralid acid CAS # 1702-17-6					
Guideline Reference Number	Guideline Study Name	MRID	Submitter (EPA Co. No.)	Status	Note
Clopyralid data requirements					
Albaugh will make offers-to-pay to the following companies that appear on the data submitters list as of 6/28/04					
Clopyralid Generic Data	Cite-All		Nufarm Americas (228)	PAY	
Clopyralid Generic Data	Cite-All		Lebanon Seaboard (961)	PAY	
Clopyralid Generic Data	Cite-All		Dow Agrosience (62719)	PAY	
Clopyralid Generic Data	Cite-All		Agvalue-Clopyr LLC (75147)	PAY	
Clopyralid Generic Data	Cite-All		Spray Drift Task Force (66607)	PAY	
Clopyralid Generic Data	Cite-All		Outdoor Res Exp Task Force (71754)	PAY	
Clopyralid Generic Data	Cite-All		Ag Reentry Task Force (71755)	PAY	
Signature	 		Name and Title: Morris Gaskins Registrations Manager		Date 6/29/04

Footnotes for Clopyralid Technical Data Matrix

Footnote 1

- 830.6314 Oxidation/Reduction: chemical incompatibility
- 830.6315 Flammability
- 830.6316 Explodability
- 830.6317 Storage Stability
- 830.6319 Miscibility
- 830.6320 Corrosion Characteristics
- 830.6321 Dielectric Breakdown
- 830.7100 Viscosity

This data is not required for Technical Grade products per Product Properties Test Guidelines OPPTS 830.1000 (e)(2)(xi)(B) Table 2

Footnote 2

- 830.6350 Formulation Process

Albaugh requests a waiver for this data requirement. Clopyralid Technical product is not deliberately formulated. See Guideline 830.1620.

Footnote 3

- 830.7220 Boiling Point/Range

Albaugh requests a waiver for this data requirement. Clopyralid acid technical is a solid.

Footnote 4

- 830.7550 Partition Coefficient, Shake Flask Method
- 830.7560 Partition Coefficient, Generator Column Method

Albaugh requests a waiver for these data requirements. Albaugh has elected to satisfy this data with the 830.7570 Liquid Chromatography Method.

Footnote 5

- 830.7860 Water Solubility, Generator Column Method

Albaugh requests a waiver for these data requirements. Albaugh has elected to satisfy this data with the 830.7840 Shake Flask Method.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 12, 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

ALBAUGH, INC
1910 EXETER, SUITE 1
GERMANTOWN, TN 38138-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 12-JUL-04. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 6, 2004

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

ALBAUGH INC
1910 EXETER, SUITE 1
GERMANTOWN, TN 38138-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 30-JUN-04. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your data submittal was found to be partially in compliance with the standards for submission of data contained in PR Notice 86-5, with the exceptions noted below. A copy of your transmittal bibliography is enclosed, annotated with the Master Record ID's (MRIDs) assigned to each document accepted. Please use these numbers in all future references to these documents.

If deficiencies were found which apply to individual accepted studies, they are listed below following the applicable MRID. Any document which has been assigned a MRID has been accepted under PR Notice 86-5. If any comments related to a MRID appear on this report, they are provided for your information and reference when preparing future submissions. Some individual documents were not acceptable, and all copies are being returned to you for correction for the reasons indicated below.

These rejected studies have been assigned separate identification numbers which are annotated on both the enclosed bibliography and the rejected document labels.

The rejected studies and their deficiencies are described below.

Rejected Study [01]:

* As per the Code of Federal Regulations title 40 part 160 -- Good Laboratory Practice Standards, studies requiring a Good Laboratory Practice (GLP) compliance statement have been expanded to include efficacy studies and physical and chemical characterization studies; see 40 CFR 160.3 and 160.135. Therefore, you must submit a statement of compliance or noncompliance with the Good Laboratory Practice Standards as described in 40 CFR 160.12.

Agri Star™

By Abaugh, Inc.

1910 Exeter Rd., Suite 1
Germantown, Tennessee 38138
866-243-4816
(901) 309-8532 (fax)

FAX

DATE: July 9, 2004
TO: JoAnne Miller **FROM:** Pam Bruce, Registrations Spec
COMPANY: EPA **FAX #:** 703-308-1825
SUBJ: Chlopyralid Technical **# OF PAGES:** 2

Joanne, Morris is currently out of the office until the morning of the 19th. I received your fax regarding the GLP Compliance Statement for the Chlopyralid Tech submission. I am a little confused on what you are requiring since we have submitted this for similar studies and have had no issues before. Never the less, I am attaching a revised GLP Compliance Statement. If this is not what you are asking for, please let me know. We do not want to hold up this submission so if it's incorrect, we'd like to withdrawal the study since it was a voluntary study.

Thanks for your help with this.

Pam Bruce
(901) 309-8122

CORPORATE OFFICE
121 NE 18th Street
Ankeny, IA 50021
515.964.9444 (Phone)
800.247.8013 (Toll Free)
515.964.7813 (Fax)

ALBAUGH, INC.

463062-00

MEMPHIS OFFICE
1910 Exeter Road, Ste. 1
Memphis, TN 38138-2971
901.309.8122 (Phone)
901.309.8532 (Fax)

FEDERAL EXPRESS

June 29, 2004

Document Processing Desk (REGFEE)
Ms. Joanne Miller (PM 23)
Office of Pesticide Programs (7504C)
US Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501

RE: Clopyralid Technical
Initial application

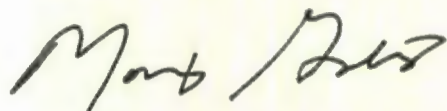
Dear Ms. Miller,

The enclosed submission is Albaugh's initial application for the above referenced product. Documents enclosed to support this application are detailed on the enclosed transmittal page.

In addition to the enclosed application for clopyralid acid technical, Albaugh will submit clopyralid end use applications in the next few weeks when acute tox studies are completed.

Please call if you have any questions.

Regards,



Morris Gaskins
Registrations Manager
Albaugh, Inc.
901-309-8122

Agri Star™
By Albaugh, Inc.

PREMIER SUPPLIER OF OFF-PATENT CROP PROTECTION PRODUCTS
www.albaughinc.com

TRANSMITTAL DOCUMENT

Name and address of submitter:

Albaugh, Inc.
1910 Exeter Road, Suite 1
Ankeny, IA 38138

Company Official: Morris Gaskins

Telephone: (901) 309-8122

Regulatory action for which this package is submitted:

Initial application to register Clopyralid Technical

Transmittal Date: June 29, 2004

List of items submitted:

- Cover letter
- Application form (8570-1)
- Confidential Statement of Formula (2 copies)
- Proposed label (5 copies)
- Data Matrix (8570-35)(Agency internal use copy)
- Data Matrix (8570-35)(Agency public record copy)
- Certification With Respect to Citation of Data form (8570-34)

Reject (01) • Summary of OPPTS 830 Series Product Properties Test Guidelines (3 copies)

46306202 • Series 830-A Product Identity & Composition, Description of Materials Used, Description of Production Process, Discussion of the Formation of Impurities and Certified Limits (3 copies)

46306203 • Series 830-A Preliminary Analysis and Enforcement Analytical Method (3 copies)

46306204 • Series 830-B Physical and Chemical Characteristics (3 copies)

